



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,638	02/27/2002	Michael Babich	21511/92177	3698
23644	7590	07/03/2006		
BARNES & THORNBURG, LLP P.O. BOX 2786 CHICAGO, IL 60690-2786			EXAMINER ROONEY, NORA MAUREEN	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/084,638

Applicant(s)

BABICH, MICHAEL

Examiner

Nora M. Rooney

Art Unit

1644

-The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

THE REPLY FILED 12 June 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: none.
Claim(s) objected to: none.
Claim(s) rejected: 17 and 22-28.
Claim(s) withdrawn from consideration: 1-16, 18-21 and 29-33.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

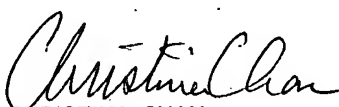
REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because:

1. Claims 17 and 22-28 stand rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,583,046 (Reference A1 of the IDS submitted 12-9-02), as evidenced by Vrtala et al. (Reference AR on the IDS of 8-6-02) for the same reasons set forth in the previous Office Action mailed 1-11-06.
2. Applicant's arguments filed 06-12-06 have been fully considered but are not found persuasive.
3. Applicant argues that a 35 U.S.C. 102 rejection is improper because all of the steps recited in claim 17 are not taught by the '046 patent and using the Vrtala reference is improper to cure the deficiencies.
4. Claim 17 requires an in vivo diagnostic test comprising administering a multimeric profilin molecule. The '046 patent teaches administering Bet v2, a profilin. The reference is silent as to whether said Bet v2 is multimeric. Vrtala recognized that when rBet v2 is placed in solution it naturally polymerizes. The Vrtala reference is only relied upon as an evidentiary reference.
5. By applicants own admission page 10 of the specification, biochemical data and computer-based modeling show that profilin can form multimers and that the multimers remain strongly attached due to strong chemical bonds. Applicant also admits that "the chemical free energy (favorable state) for two profiling molecules is to self associate." The chemical free energy state is an inherent property of the molecule. When Bet v2 is placed in solution, as required to administer to a subject in non-lyophilized form, it polymerizes due to the physical properties of the molecule. The Vrtala reference teaches on page 914 "it could be shown that rBet v2 formed polymers through disulfide bonds" and that "The tendency of recombinant Bet v 2 to form polymers through disulfide bonds under non-reducing conditions was demonstrated by SDS-PAGE, immunoblotting and blot overlays." This reference has been used simply to illustrate an already described process showing inherent properties of the molecule.
6. Applicant puts forth on page 10 of the specification that "The ability of plant profilin to form clinically relevant multimers from human and a variety of plant species is a novel aspect of the present invention. However, applicant admits on page 11 of the specification that "established methods of profilin isolation have often yielded extraneous and unidentified proteins (discussed in Babich, et al., 1996) that are 2 times the recognized size of the 12-15 kDa cytoskeletal molecule." The court in Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999) held that "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." The prior art shows inherent characteristics of profilin that may have been unappreciated, but are nonetheless inherent properties of the molecule and are not patentably distinct.
7. Applicant argues that Vrtala teaches away from the claimed invention. However, the reference is being relied on to show inherent properties of the profilin Bet v2 molecule, not observations of the level of allergenicity of the profilin.
8. Applicant's argument that the form of rBet v2 injected into the animal models was likely monomeric is without merit. On page 914 in the Vrtala Methods section relied upon by applicant for this assertion, "the recombinant protein produced a single peak in the chromatogram" is referring to the rBet v1 protein, not the rBet v2 protein.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.
10. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.
11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Nora M. Rooney, M.S., J.D.
Patent Examiner
Technology Center 1600
June 29, 2006


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600